

BLOOD PRESSURE MONITOR
TENSIONE

MANUAL BOOK

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Foreword

Please read the User's Guide carefully before using this product. The User Manual that describes the operating procedure must be strictly followed . This detailed guide introduces the steps to be taken when using the product, operations that may result in abnormality, the risk of causing personal injury and damage to the product and other content, see chapter for details. Anomalies or personal injury and device damage arising from the use, maintenance, storage do not follow the requirements of the User Guide, our company is not responsible for the guarantee of safety, reliability and performance! The manufacturer's warranty service does not cover such faults!

Our company has factory records and user profiles for each device, users enjoy free maintenance service for one year from the date of purchase. To make it easier for us to provide you with comprehensive and efficient maintenance services, be sure to return the warranty card when you need repair service.

⚠Note: Please read the User Manual carefully before using this product.

Described in this User's Guide according to the practical situation of the product. In the case of software modifications and enhancements, the information contained in this document is subject to change without notice.

Warning Items

Before using this product, you should consider the safety and efficacy described below:

- Each measurement result is explained in combination with clinical symptoms by a qualified doctor.
- Reliability and operability of using this product whether it complies with this operation manual and related maintenance instructions.
- The intended operator of this product may be the patient.
- Do not perform maintenance and service while the device is in use.

 **Warning: Replacing accessories not provided by our company may cause errors to occur.**

Changing the SpO₂ adapter, cuff, or probe at will may result in incorrect measurement results. Without our company or other approved maintenance organization, trained service personnel should not attempt to maintain the product.

Operator's responsibility

- ① The operator must read the User Manual carefully before using this product, and strictly follow the operating procedures of the User Guide.
- ② Fully consider safety requirements during product design, but the operator should not neglect patient observation and the state of the machine

③ The operator is responsible for providing our company with the conditions of use of the product.

Responsibility for our company

- Our company is responsible for providing quality products that comply with the company's product standards.
- Our company will provide circuit diagrams, calibration methods and other information upon user's request to assist suitable and qualified technicians to repair the parts designated by our company.
- Our company has the responsibility to complete the product maintenance according to the contract.
- Our company has a responsibility to respond to user needs in a timely manner.
- In the following cases, our company is responsible for the impact on the security, reliability and performance of the device:

Assembly, addition, debugging, modification or repair is carried out by personnel approved by our company.

The electrical facilities in the room meet the relevant requirements and the equipment is used according to the User's Guide.

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Chapter 1 Security Precautions

- In order to use it properly, please read "Security Measures" carefully before using it.
- Operators do not require professional training, but should use this product after fully understanding the requirements in this manual.
- In order to prevent users from suffering damage or loss due to improper use, please refer to "Safety Measures" and use this product properly.

⚠ Notes ⚠

If not used properly, there is a possibility of damage to personnel and property.

Good damage means damage to homes, property, pets and pets.

⚠ Contraindications ⚠

Not.

⚠ Warning ⚠

- You should not take NIBP measurements on patients with sickle cell disease or in any condition whose skin is damaged or expected to be damaged.
- For patients with severe coagulation disorders, whether to automatically measure blood pressure should be based on clinical evaluation, as friction of the limb with the cuff may increase the risk of hematoma.

- For patients with severe blood circulation disorders or arrhythmias, please use the device under the guidance of a doctor. If the arm is pinched during measurement, it may cause acute internal bleeding or inaccurate measurement results.

Measurement Limit

For different patient conditions, oscillometric measurements have certain limitations. Measurement is looking for a regular pulse of arterial pressure. In those circumstances when the patient's condition makes it difficult to detect, the measurement becomes unreliable and the measurement time increases. Users should be aware that the following conditions may interfere with measurements, making measurements unreliable or taking longer to derive. In some cases, the patient's condition makes measurement impossible.

Patient Movement

Measurements are unreliable or cannot be performed if the patient is moving, shivering or having seizures. This movement can interfere with pulse detection of arterial pressure. In addition, the measurement time will be extended.

Heart arrhythmia

Measurements are not reliable and may not be possible if the patient's cardiac arrhythmia has caused an irregular heartbeat. Thus, the measurement time will be extended.

heart-lung machine

Measurements would not be possible if the patient was connected to a heart-lung machine.

Pressure Change

Measurements will be unreliable and impossible if the patient's blood pressure changes rapidly over a period of time during which the arterial pressure pulse is analyzed to obtain a measurement.

Severe shock

If the patient is in severe shock or hypothermia, measurement is unreliable because reduced peripheral blood flow will result in reduced arterial pulse.

Extreme Heartbeat

Measurements cannot be taken at a heart rate less than 30 bpm and greater than 250 bpm.

Round Patient

A thick layer of body fat will reduce measurement accuracy, because fat originating from arterial shock cannot access the cuff due to damping.

⚠️Warning⚠️

Self-diagnosis and treatment using measurable results may be dangerous. Follow your doctor's instructions.

Please hand measurement results to a doctor who knows your health and accepts the diagnosis.

For Babies and people who can't express themselves, please use the device under the guidance of

a doctor.

Otherwise, it may lead to accidents or clashes.

Please do not use for any other purpose except BP measurement.

Otherwise, it may cause accidents or obstacles

Please use a special cuff.

Otherwise, the measurement results may be incorrect.

Please do not leave the cuff in an overly high state for a long time.

Otherwise, it may pose a risk.

Do not use the device if flammable anesthetic gas is mixed with air or nitrous oxide.

Otherwise, it may pose a risk.

If liquid splashes onto the device or accessories, especially when liquid may enter the tubing or device, discontinue use and contact service.

Otherwise, it may pose a risk.

Dispose of packaging materials, comply with applicable waste control regulations and keep out of reach of children.

Otherwise, it may cause harm to the environment or children.

Please use accessories approved for the device and check that the device and accessories are functioning properly and safely before use.

Otherwise, measurement results may be inaccurate or accidents may occur.

When the device is accidentally damp, it must be placed in a dry and ventilated place for a certain period of time to remove moisture.

Otherwise, the device may be damaged by moisture.

Do not store and transport the device outside the specified environment.

Otherwise, it may cause measurement error.

It is recommended that you regularly check for damage to your device or accessories, if you find any damage, stop using it, and contact a hospital biomedical technician or our Customer Service immediately. Do not disassemble, repair, and modify the device without permission.

Otherwise, it cannot be measured accurately.

This device cannot be used on mobile transport platforms.

Otherwise, it may cause measurement error.

This device cannot be used on an inclined table.

Otherwise, there is a risk of falling.

Dispose of packaging materials, used batteries and end-of-life products in accordance with local laws and regulations. Expired products and materials are properly disposed of by the user in accordance with the authority's decision.

Replacing accessories not provided by our company may result in errors.

Without our company or other approved maintenance organization, trained service personnel should not attempt to maintain the product.

This device can only be used for one test object at a time.

If small parts of the device are inhaled or swallowed, please consult a doctor immediately.

Devices and accessories are processed with allergenic materials. If you are allergic to it, stop using this product.

After pressing the power button, if the device has display errors such as white screen, blurry screen or no display content, please contact our company .

The device must meet the standard IEC 80601-2-30: Special requirements for basic safety and critical performance of automatic non-invasive tensimeters.

1.1 Operation for AC Adapter

⚠ Notes ⚠

The device can be powered by a power adapter that is part of the medical electrical system. Be sure to use the dedicated medical grade power adapter of this device.

Otherwise, it may cause problems

The dedicated power adapter must use AC 100V~240V

Otherwise, it may cause fire or electric shock.

When there is damage to the special power adapter plug or cable, please do not use it .

Otherwise, it may cause fire or electric shock.

Please do not plug or unplug the adapter from the socket with wet hands.

Otherwise, it may cause electric shock or injury.

1.2 Operation for Battery



Please use 4 "AA" size batteries, do not use other types of batteries.

Otherwise, it may cause a fire.

New and old batteries, different types of batteries cannot be turned off.

Otherwise, it may cause battery leakage, heat, rupture, and damage to the Electronic Sphygmomanometer.

Please do not enter the battery positive and negative incorrectly. When the battery runs out, replace it with four new batteries at the same time .

Please remove the battery when you do not use the device for a long time (3 months or more) .

Otherwise, it may cause battery leakage, heat, rupture, and damage to the Electronic Sphygmomanometer.

If battery electrolyte gets into your eyes, rinse immediately with plenty of clean water.

Will cause blindness or other danger, must immediately go to the nearest hospital for treatment.

If battery electrolyte adheres inappropriately to skin or clothing, rinse immediately with plenty

of clean water .

Otherwise, it may injure the skin.

Advice

Do not hit or drop the device;

Do not inflate before the cuff wraps around the arm;

Do not bend the cuff and air tube forcibly.

Function description:

Sphygmomanometer applies to non-invasive measurement of blood pressure and SpO₂ of humans (adults, children, neonates), using three-user mode, each user can store 100 items of measurement result records at most. Each record includes detailed measurement time, systolic pressure, diastolic pressure, average pressure, pulse and record number, etc. With 2.8inch color LCD screen, clear interface, data review function is complete. Users can implement ON/OFF, manual measurement, system settings, parameter changes and other operations with seven buttons located on the front panel of the device.

The sphygmomanometer uses voice and visual prompts, when the battery power is low, the buzzer will buzz intermittently and the LCD screen displays "Low Power" to prompt the user to change the battery. When the measurement data exceeds the set prompt limit, the font color of the measurement result will turn red and an audible prompt will occur, the user can open and close the voice prompt according to the need. With time power off function, if there is no operation and SpO₂ measurement, the device will

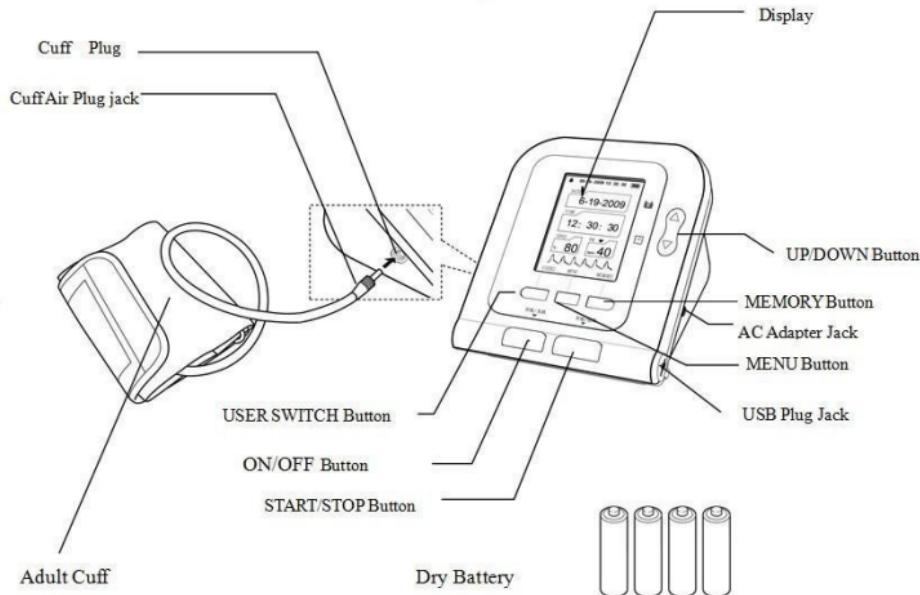
turn off automatically after 2 minutes. With USB interface, User can send measurement result to PC.
See the associated software help or description for a specific operation.

Purpose:

This device is applicable for non-invasive measurement of human blood pressure and SpO2 (optional).
Record blood pressure parameter values to provide a reference for health care professionals.

Chapter 2 Main Unit

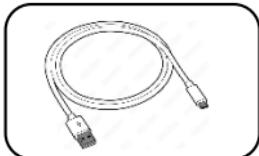
Production is in the package. Open the package and confirm whether the **production** is intact.



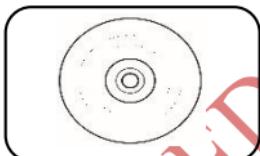
Accessories:

Specifications: leg circumference 22-32 cm (middle of the upper arm), please choose the appropriate cuff when measuring the child or other leg circumference .

USB Data Line



CD software



User Manual



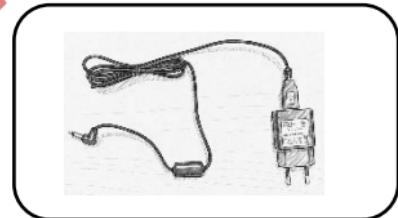
Optional accessories :

AC Adapter

Inputs: Voltages: AC 100 V~240 V

Frequency: 50 Hz /60 Hz

Output: DC 5.0-6.0 V 1.0-2.0 A



SpO₂ probe: SpO₂ probe

A. SpO₂ measurement

Range:0% ~100%

Error: 70~100 %: $\pm 2\%$; 0~69 %; not specified

Resolution: 1 %

Note: because the SpO₂ probe measurements are statistically distributed, only about two thirds of the SpO₂ probe measurements can be expected to be within ± 1 SD of the values measured by the CO-OXIMETER.

B. Pulse measurement

Range: 30bpm~250bpm

Error: ± 2 bpm or $\pm 2\%$ (choose bigger)

Resolution: 1 bpm

C. Optical sensor: red light (wavelength: 660 nm, output power less than 6.65 mW) infrared light (wavelength: 880 nm, output power less than 6.75 mW). Optical sensors are light-emitting components that affect other medical devices that use this wavelength range. This information may be useful to doctors who perform optical therapy.

D. Error in weak charge state: SpO₂ and pulse rate can be displayed correctly when the charge-pulse ratio is 0.4%. The SpO₂ error is $\pm 4\%$; when the measuring range is 30 bpm~100 bpm, the pulse rate error is ± 2 bpm; when the measuring range is 100 bpm~250 bpm, the pulse rate error is $\pm 2\%$.

Note:



optional probe of the Sphygmomanometer is the integrated SpO₂ probe, the measuring part is integrated with the probe;

life of the integrated SpO₂ probe is three years.

Cuff:

Choose the right cuff based on the patient's upper arm circumference, there are several suitable cuffs (leg circumference range, center of upper arm)

range of limb circumference is 6 - 11 cm

range of leg circumference is 18 - 26 cm

range of leg circumference is 22 - 32 cm

⚠ Notes ⚠

Cufflinks are consumables. Calculate by measuring 6 times a day (3 times every morning and evening), the service life of the cuff is about 1 year. (using our experimental conditions)

In order to measure blood pressure correctly, please change the cuff in time.

cuff leaks, please contact our company to buy a new one. Cufflinks purchased separately do not include an air inlet hose plug. When replacing, do not remove the air duct plug, install it in a new cuff.

⚠Notes ⚠

If the product and accessories described in this manual are beyond the period of use, they must be disposed of in accordance with the relevant product handling specifications. If you would like more information, please contact our representative company or organization.

Chapter 3 External Interface

⚠ Notes ⚠

When removing the NIBP cuff, please pull out the plug at the front of the throat to pull it out.

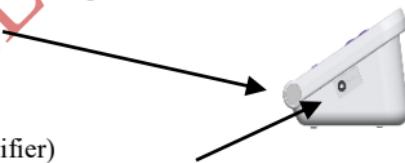
- ① Cuff socket ( is the cuff identifier)



Left side

The right side of the device is the USB socket and the power adapter socket

- ① socket ( is USB identifier)



Right side

- ② Power adapter socket ( is power socket identifier)

⚠ Notes ⚠

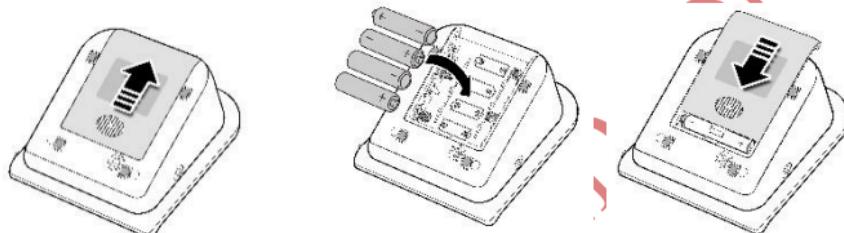
All analog and digital equipment connected to this device must be certified to IEC standards (such as IEC60950: Safety-information technology equipment and IEC60601-1: Medical-Safety electrical equipment), and all equipment must be connected in accordance with the requirements

of a valid version of the IEC60601 system standard. -1-1. The person connecting additional equipment to the signal input and output ports is responsible for whether the system complies with the IEC60601-1 standard.

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Chapter 4 Battery/AC Adapter Installation

The product can use a battery or an AC adapter as a power source.



- ①
- ②
- ③

4.1 Battery Installation

- ① Remove the battery cover in the direction of the arrow.
- ② Install the "AA" battery according to the polarity $\oplus \ominus$.
- ③ Slide to close the battery cover.

" icon : the battery will run out. Replace with four new batteries (same type) at the same time.

Tests at low power may cause data drift and other problems.

Turn off the unit before replacing the battery.

⚠ Notes ⚠

When the battery reaches the end of its useful life, or if the battery is found to have an odor, deformation, discoloration or distortion, stop using the battery and dispose of the used battery according to local regulations, otherwise it will cause environmental pollution.

4 .2 Use of power adapter

1. Connect the sphygmomanometer and power adapter. Insert the power adapter plug into the power adapter socket on the right side of the device.
2. Please insert the power adapter plug into the 100V~240V AC socket.

⚠ Notes ⚠

The device can be disconnected from the power supply network by unplugging the adapter.

When disconnecting the power supply, first disconnect the mains socket and the regulated power supply, then disconnect the regulated power supply and sphygmomanometer.

Be sure to use a dedicated medical grade power adapter.

⚠ Notes ⚠

When the regulated power supply and battery are both used at the same time, the battery power will not be consumed.

Replace the power supply and battery set as power supply when the device is off, otherwise the

device may turn off due to a power failure.

The device can be used normally after power on, without waiting for the device to be set up.

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Chapter 5 Button Functions

All operations to Electronic Sphygmomanometer via buttons. The names of the buttons are on it. They:

-  **ON/OFF】** ON/OFF button. Press this button to turn on/off the device.
-  **START/STOP】** Press to inflate the cuff and start the blood pressure measurement. During measurement, press to cancel the measurement and deflate the cuff.
-  At all levels of the interface, the three buttons correspond to the text instructions below the LCD screen, pressing any button will perform the appropriate function, for example: MENU 【 ENTER LIST】【 USE R】 dst.
-  The up and down buttons, respectively, perform the function of moving the cursor up and down, changing parameters and changing statuses.

Chapter 6 Setting the Date and Time

It is important to set the date and time after power on.

Electronic Sphygmomanometer can automatically save measurement results with date and time.

If the battery is discharged or disconnected, it's time to stop.

At this time, please reset the date and time.

The Electronic Sphygmomanometer stores the measurement results of three users automatically, and up to 100 items for each user. If the date and time are set correctly, the date and time when the measurement will be correct in memory, otherwise it may not be correct. The results can be uploaded to a PC via USB and processed with PC software.

1、 There are two timing modes:

(1) When using the Sphygmomanometer for the first time or after the Sphygmomanometer is placed without power supply for a certain time (more than 3 minutes), after power on, there is a time error prompt on the main interface, set the date and time by buttons 【 UP, DOWN and ENTER】 _ _

(2) Press the MENU】 button on the main interface to enter the system menu, then enter SYSTEM TIME】 , the current time will be displayed on the screen. Set the date and time with the UP, DOWN and ENTER buttons.

2、 After setting, select the CONFIRM】 option and press the ENTER】 button to confirm the setting value. If you do not want to change the time, select the EXIT】 option and press the ENTER】 button

to return to the previous menu.

⚠ Notes ⚠

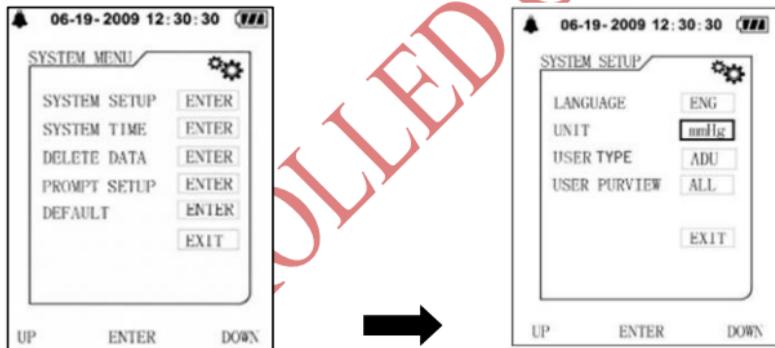
The range of years is 2010-2099. When the year reaches 2099, pressing the UP button will return to 2010

Chapter 7 About Unit

There are two units: "mmHg" and "kPa".

The default is: "mmHg".

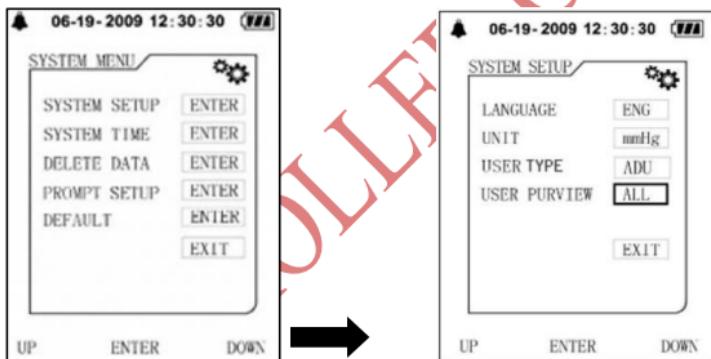
SYSTEM SETUP】 submenu in the SYSTEM MENU】 then select the UNIT option to switch the unit between "mmHg" and "kPa".



Chapter 8 Switching Users

The Electronic Sphygmomanometer stores the measurement results of three users automatically, and up to 100 items for each user.

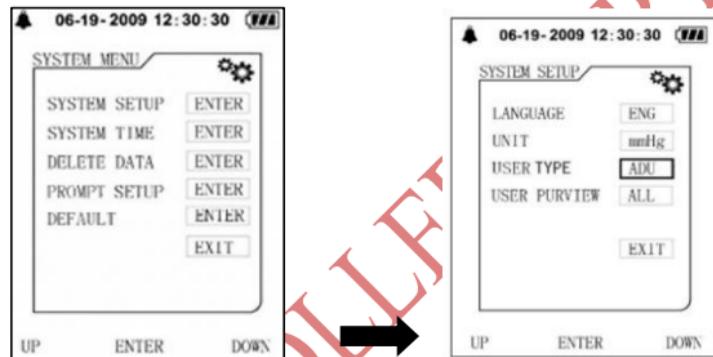
Press the 【USER】 button in the main interface to switch users. Or press USER PERVIEW】 item in SYSTEM SETUP】 menu to switch users.



⚠ Notes ⚠

When USER PERVIEW】 is set to ALL】 , the current user can be switched under the main interface; when set to a specific user, it will not be able to switch under the main interface.

User type can be set to adults, children and neonates three different types, the setting method is as follows:



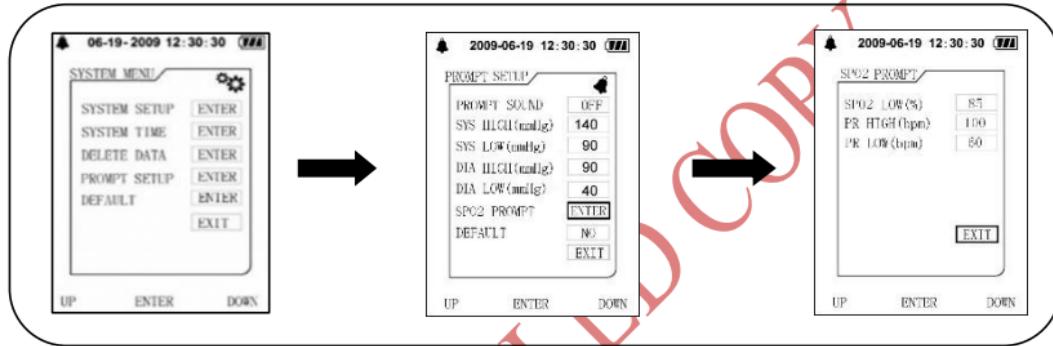
Chapter 9 Function Prompt Exceeded the Limit

The sphygmomanometer has two kinds of reminder methods: technical parameter over-limit prompt and physiological parameter over-limit prompt.

9 .1 Physiological parameters exceed the prompt limit

The sphygmomanometer has an over-limit prompt function, the user can press the 【MENU】 key to enter the system menu, select the 【 PROMPT SETUP】 option to enter the interface, then set the blood pressure limit value. When the BP measurement result is higher than the upper limit or lower than the lower limit and prompts ON, a physiological prompt will occur; in the interface 【 PROMPT SETUP, select the option 【SpO₂ PROMPT to enter the interface, when the SpO₂ measurement result is higher than the high limit or lower than the low limit and the ON prompt, the physiological prompt will appear.

In the physiological state of the prompt, press any key to cancel the prompt and not affect the next prompt; The prompt can be permanently closed with the switch prompt from the setup prompt menu until the switch prompt is reopened.



9.2 Technical parameters exceed the prompt limit

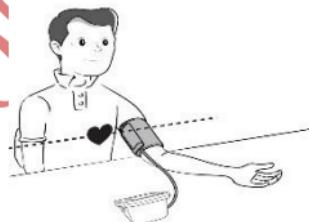
When the power is low and the prompt is ON, a prompt will appear. This prompt cannot be canceled unless it is closed or the power is changed.

Chapter 10 Method of Using the Sphygmomanometer

10.1 Accurate Measuring Method

Measurement in a calm and relaxed state.

1. Adopt a comfortable sitting position, using your back and arms to support your body.
2. Place your elbows on the table, palms facing up and body relaxed.
3. The cuff is in line with your heart.
4. Feet flat on the floor, and do not cross your legs.



⚠ Suggestion ⚠

Try to take your blood pressure at the same time each day with the same arm and the same pose for consistency.

The high and low position of the cuff will cause changes in the measurement results.

Do not touch the sphygmomanometer, cuff, and throat during measurement.

Measurements should be taken in a quiet and relaxed place.

Keep still 4~5 minutes before measurement.

Do not talk or move during the measurement. Relax the body, do not allow muscle activity.

Wait 4~5 minutes between measurements.

Do not use precision instruments near the sphygmomanometer.

⚠ Warning ⚠

When repeatedly measuring, an accurate blood pressure value may not be measured due to congestion in the arm. Please measure after the blood flow is smooth.

Repeated measurements for long periods of time, limb rubbing against the cuff may be accompanied by purpura, ischemia, and nerve damage. When measuring the patient, it is necessary to frequently check the color, warmth and sensitivity of the distal extremity. Once abnormalities are observed, place the cuff in another position or stop the blood pressure measurement immediately.

Please use the device in an environment with suitable temperature and humidity (see Chapter 19), otherwise it will cause measurement error.

Do not twist or wrap the airway tube. This can cause constant pressure on the cuff which can block blood flow and cause serious damage to the patient.

Do not use the cuff on the injured area, which will cause more serious damage to the area.

Do not use the cuff in areas where the treatment is in a vein or arteriovenous junction. This can cause a temporary blockage of blood flow and cause injury to the patient.

Do not use the cuff on the mastectomy side.

When using the cuff to apply pressure, some bodily functions may be temporarily weakened. Do not use medical electrical measuring equipment at the appropriate arm position.

Do not move during the measurement, it will have a delayed effect on the patient's blood flow.
The device must be placed for 2 hours from the minimum storage temperature until it is ready for its intended use.
The device must be placed for 4 hours from the highest storage temperature until it is ready for its intended use.

Notes

The following conditions can also cause changes in blood pressure measurement values.

Take measurements within one hour after eating or after drinking alcohol, coffee or after smoking, exercising, bathing;

Using wrong postures such as standing or lying down, etc.;

The patient speaks or moves his or her body during the measurement;

When measuring, the patient is nervous, excited, emotional instability;

The room temperature rises or falls sharply, or the measurement environment changes frequently;

Measurements in moving vehicles;

The high and low position of the cuff will cause changes in the measurement results;

Continuous measurement for a long time.

10.2 Applying the Cuff

Both left and right arms can be measured.

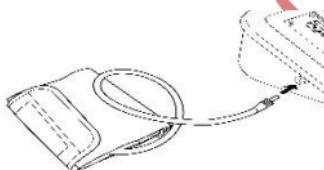
Bare on your sleeve or clothing that fits perfectly during the measurement.

Perform the operation in a room with a comfortable temperature.

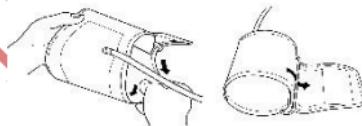
When measuring, remove heavy clothing instead of rolling up sleeves.

To measure accurately, pay attention to the correct application of the cuff (left arm).

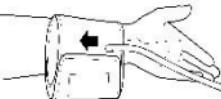
- ① Insert the sleeve cuff air plug into the sphygmomanometer cuff socket.



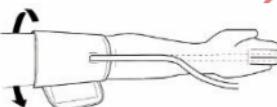
- ② Stretch the cuff into the barrel so that the sleeve fits into the barrel



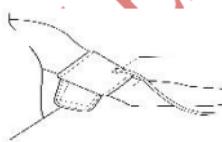
- ③ Left arm through the cuff, the air tube of the cuff will pass through the top of your palm.



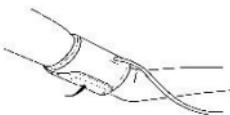
- ④ Wrap the cuff around your upper arm. Make the air tube inside the forearm and in line with your middle finger.



- ⑤ The bottom of the cuff should be about 2cm~3cm above the elbow.



- ⑥ Fixed with clothing, and wrapped in tight cuffs, sleeves and cuffs should not have gaps.



10.3 BP Pengukuran Measurement

Users can be set to three different types (adult, child and newborn). Set it through the USER TYPE option in the SYSTEM SETUP 】 menu.

⚠ Notes ⚠

When the patient is a newborn, please select the newborn mode and select the appropriate cuff size to measure, otherwise it may harm the patient.

Press the **START/STOP button** to start the measurement.

During the measurement, please keep the correct pose and calm state, do not move.

If you want to cancel the measurement

Press the **START/STOP button**, the device will stop inflating, and release the air from the cuff.

Confirm Measurement Value

The measurement values can be saved automatically, using the [memory function] (see Chapter 11).

*Self-diagnosis and treatment using measured results may be harmful. Follow your doctor's instructions.

⚠ Notes ⚠

■ Wait at least 4-5 minutes between measurements

When repeatedly measuring, an accurate blood pressure value may not be measured due to congestion in the arm. Please measure after the blood flow is smooth.

- When several factors affect the measurement result in the measurement process, an error message will appear on the screen, you can avoid the malfunction and restart the measurement.
- The minimum value of the patient's physiological signal is the minimum that the device can measure. The device may obtain inaccurate measurement results when operated below the minimum amplitude or minimum value of the patient's physiological signal.

In the state of physiological parameters over-limit prompt is not triggered, press any key to perform the corresponding key function; in the audio prompt state, press any key (except the ON/OFF】 button) to clear the audio prompt .

Release the cuff, press the ON/OFF】 button to turn off the device.

Chapter 11 Memory Function

The sphygmomanometer is designed to store blood pressure, pulse rate and the date and time when it was measured, which is up to 100 measurements. If 100 measurements have been saved, the earliest result will be deleted when saving 101 measurement result groups.

11.1 Review Memory Value

1. In the main interface (the start-up interface), press the MEMORY key to view the latest measured values in large fonts with serial numbers from 1 to 100.
2. Press the 【UP】/【DOWN】 button to change the previous measurement value circularly.
* Exact numbers indicate that no measurement results can be displayed.
3. Press the 【LIST】 button to display the data list interface.
4. Press the TREND】 button to display the trending interface.



End to display the measurement value:

Press the EXIT】 button to return to the main interface or hold down the 【ON/OFF】 button to turn off the device.

11.2 Delete Memory Value

User can delete all user memory values instead of deleting one memory value separately.

1. Press the MENU button to enter the system menu, select the DELETE DATA】 option to enter the interface, select the user whose data will be deleted, after confirming again, all the measurement results

of the selected user will be deleted.

2. Complete Operation

Select 【CONFIRM】 or 【EXIT】 to return to the previous menu, or hold down the 【ON/OFF】 button to turn off the device.

Chapter 12 SpO2 Measurement Function

Precautions during SpO2 Measurement:

⚠ Notes ⚠

- Make sure the nails cover the light. The probe cable should be on the back of the hand. Improper placement of the probe or improper contact with the test site will affect the measurement.
- The SpO2 value is always displayed in a fixed place.
- The test site must not use external coloring agents (such as nail polish, dyes or colored skin care products, etc.), otherwise it will affect the measurement.
- Fingers that are too cold or too thin may affect the measurement accuracy, please insert thicker fingers such as thumb or middle finger deep enough into the probe.
- The SpO2 probe is suitable for both children and adults (not suitable for infants and newborns). The device may not apply to all patients. If you cannot achieve a stable reading, discontinue use.
- Data averaging and signal processing will delay the SpO2 display and data value transmission. The measurement data update time is less than 30 seconds, when the signal attenuation, weak perfusion or other interference appears, it will result in an increase in the dynamic data average time, which depends on the PR value.
- The PLETH waveform is not normalized, which is used as an indicator of signal incompleteness. So

that the accuracy of the measured value can decrease if the waveform tends to be not smooth and stable. When the waveform tends to be smooth and stable, the reading is the optimal value, and the current waveform is the most standard.

- The temperature of the contact surface of the device with the body is less than 41 °C, and this temperature value is measured by a temperature measuring device.
- The device does not provide an alarm function that exceeds the limit, so it cannot be used where the function is required.
- The SpO₂ probe is calibrated before it leaves the factory. No need to calibrate during maintenance.
- The SpO₂ probe is calibrated to show functional oxygen saturation.
- The SpO₂ probe and photoelectric receiving tube should be arranged so that the subject's arterioles are positioned in between. Make sure the optical path is free of optical obstructions such as rubber cloth, to avoid inaccurate measurements.
- Since measurements are based on arteriolar pulses, substantial pulsed blood flow from the subject is required. For subjects with a weak pulse due to shock, low ambient/body temperature, heavy bleeding, or use of vascular contracting drugs, the SpO₂ (PLETH) waveform will decrease. In this case, the measurement will be more sensitive to interference.
- The accuracy of the readings under weak perfusion was verified using signals from the patient simulator. SpO₂ and pulse rate values vary within the measurement range due to various weak signal

conditions and are compared with the actual SpO₂ and pulse rate values of the known input signal.

- Claims of SpO₂ accuracy must be supported by clinical research measurements spanning the entire spectrum. By artificially inducing to different levels of stable oxygen, making it in the range of 70% 100% SpO₂. Use secondary standard SpO₂ measuring equipment for comparison to collect SpO₂ values along with the product being tested, create paired data groups for accuracy analysis.
- The clinical report recorded data on 12 healthy volunteers, including 6 women and 6 men. The age of the volunteers ranged from 21 to 29 years. Skin color is distributed from dark to light, including 3 dark blacks, 2 medium blacks, 5 light skins, 2 whites.
- When using the device, keep it away from instruments that can generate strong electric or magnetic fields. Using the device in an unsuitable environment may cause interference to nearby radio equipment or affect its operation.
- If necessary, please go to our company's official website to download a list of SpO₂ probes and extension cables that can be used with this device.

⚠ Warning ⚠

- Check if the SpO₂ probe wire is in normal condition before measuring. After unplugging the SpO₂ probe from the socket, the "SpO2%" and "bmp" on the screen will disappear.
- Do not use the SpO₂ probe after the package or probe has been found to be damaged. Instead, you

must return it to the vendor.

- The included SpO₂ probe is only suitable for use with this device. This device can only use the SpO₂ probe described in this manual. It is the operator's responsibility to check the compatibility of the SpO₂ device and probe (and extension cord) prior to use. Incompatible accessories may result in decreased device performance or cause injury to the patient.
- SpO₂ probe is a medical product that can be used repeatedly.
- The measured values may appear normal in the testee who has anemia or dysfunctional hemoglobin (such as carboxyhaemoglobin (COHb), methaemoglobin (MetHb) and sulphaemoglobin (SuHb)), but the testee may appear hypoxic, it is advisable to carry out further assessment according to the situation and clinical symptoms.
- Pulse oxygen has only reference significance for anemia and toxic hypoxia, because some patients with severe anemia still show better pulse oxygen measurements.
- Measurement accuracy may be affected by interference with electrosurgery equipment.

SpO₂ probe to the extremity with an arterial catheter or receive intravenous injection.

Do not take the SpO₂ measurement and the NIBP measurement on the same leg at the same time, as obstruction of blood flow during NIBP measurement can affect the SpO₂ reading.

Excessive movement (active or passive) of the subject or strenuous activity may affect measurement accuracy.

Excessive ambient light may affect the measurement results, such as surgical light (especially xenon light sources), bilirubin lamps, fluorescent lamps, infrared heaters and direct sunlight, etc. To prevent interference from ambient light, be sure to position the probe properly and cover the probe with an opaque material.

Measured values may not be accurate during defibrillation and for a short time after defibrillation, because the SpO₂ probe does not have a defibrillation hold function.

People who are allergic to silicone, PVC, TPU, TPE or ABS cannot use this device.

For some special patients, the examination should be more careful in the measurement section. The probe cannot be cut in edema and soft tissue.

Do not look directly at the luminescent components when the device is turned on (infrared light is not visible), even if it is for maintenance purposes, or it may be bad for the eyes.

Feelings of discomfort or pain may occur with continuous use of the SpO₂ probe, especially for patients with microcirculation barriers. It is recommended that measurements are not taken in the same position for more than 2 hours. Continuous and prolonged measurement can increase the risk of undesirable changes in skin characteristics, such as extreme sensitivity, redness, blistering or pressing necrosis, especially for neonates or patients with impaired perfusion and changes or immature skin shape. Particular attention should be paid to checking the position of the probe placement according to changes in skin quality, correct optical alignment, and method of insertion. Check the attachment position

periodically and change it as the leather quality deteriorates. More frequent examinations may be required due to differences in the patient's condition.

Some functional test models or patient simulators can measure the accuracy of devices that reproduce calibration curves, but cannot be used to evaluate the accuracy of these devices.

refer to the relevant medical literature for detailed clinical limitations and contraindications,
This device is not used for medicinal purposes.

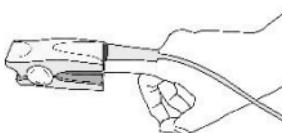
Do not use the SpO₂ probe during MRI and CT scans, as the induced current may cause burns.

When the device is ON, if the power is cut off for more than 30 seconds, the SpO₂ probe does not require operation after the power is restored, after the device is turned on, make sure the SpO₂ probe can be used normally.

probe can be used before/after exercise, but is not recommended for use during exercise.

Chapter 13 Method of Measurement of SpO₂

- 1) Attach the SpO₂ probe to the right place of the patient's finger as shown below.



Place the SpO₂ probe

- 2) Plug the SpO₂ probe cable connector into the USB socket on the bottom right of the device. The main interface will switch to the SpO₂ interface. This operation does not carry affection to other functions.

⚠ Notes ⚠

SpO₂ display range : 0% ~100%, PR display range: 30 bpm (beats/min) ~ 250 bpm (beats/min)

If the SpO₂ is working abnormally, after connecting the SpO₂ probe to the device, the device will not switch to the SpO₂ interface or no data is displayed under the SpO₂ interface.

Measurement Limit

During operation, the accuracy of SpO₂ readings may be affected by:

- High frequency electromagnetic interference such as interference from electrosurgery equipment

connected to the system.

- Intravenous dye.
- Excessive patient movement.
- Outside light.
- Incorrect installation of the SpO₂ probe or wrong patient contact position.
- SpO₂ probe temperature (optimal temperature range: 28°C ~ 40°C).
- Place the SpO₂ probe on the extremity that has a blood pressure cuff, arterial catheter, or intravascular line.
- Dysfunctional hemoglobin concentrations, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb).
- SpO₂ is too low, circumferential perfusion is poor in the measured section.
- Intravascular dyes (such as indocyanine green or methylene blue), skin pigmentation.
- It is required to use the SpO₂ probe provided by our company, contact our sales department if needed.

Chapter 14 Software Installation

1 4 .1 Editor's Request

Processor: Intel Celeron 2.5G or more

Operation System: Windows XP /Win7/Win8

EMS memory: 1GB and more

Hard Disk: 250G or more

Display: 17 inches or more

CD-ROM

USB: 2 or more

Resolution of printer: 600 DPI

1 4 .2 Software Installation

1. Place the CD-ROM in the CD-ROM compartment located on your computer.
2. If AutoPlay for CD is enabled, place the CD in the reader and follow the instructions as they appear on the screen; otherwise follow the installation instructions below:

Open Windows Explorer.

Click on the root directory of the CD-ROM.

Double-click the file management software.

Follow the on-screen instructions.

See "Software Help" for details on PC software operating methods.

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Chapter 15 Error Message

An error message will be displayed on the screen if something goes wrong while measuring. The causes and solutions are shown as follows:

Error Message	Reason	Solution
Self test failure System failure	Abnormal function	Please contact us
Loose cuff	The cuff is not connected properly.	Connect the cuff properly (see Chapter 10)
Air leak	Remove the cuff plug	Ensure that the cuff plug is securely attached to the throat (see Chapter 10)
Air pressure error	Air pressure error	See troubleshooting
Weak signal	The pulse signal is too weak or the cuff is loose.	Connect the cuff properly (see Chapter 10)
Excessive pressure	Clogged or pinched cuff	Connect the cuff properly (see Chapter 10)

Excessive movement Over reach Saturated signal	Signal range is too large due to arm or body moving or other reasons when measuring	Keep arms, body still, measure again
Time out	It took too long	

Chapter 16 Troubleshooting

Abnormal Phenomenon	Causes	Solutions
BP measurement value is too high or too low.	The cuff is not connected properly.	Connect the cuff properly (see Chapter 10)
	Talk or move your arm when measuring	Keep still and restart measurement
	Clothes put too much pressure on the arms	Take off the pressing clothes arm, and restart the measurement
No pressure	Cuff leak	Buy new cufflinks
	The windpipe of the cuff is not properly connected to the cuff	Connect properly
	Cuff not inflated	Stop using the device and contact us
Cuff deflates in no time	Loose cuff	Install the cuff correctly
It can't take measurement when pressing measurement button		Turn on the power again and restart the measurement

Shut down suddenly while inflating	Not used for a long time, the battery may run out due to the changing temperature	Replace all four batteries with new ones.
Hold on/off button but can't start device	Battery power may run out	Replace all four batteries with new ones.
	Reverse battery polarity	Check the battery mount for correct battery polarity placement.
Cuff inflation starts before pressing the measuring button or never stops inflating while measuring		Pull the cuff to deflate. Stop using the device and contact us.
Cuffs never deflation		Pull the cuff to deflate. Stop using the device and contact us.
Air pressure error	No deflation or error deflation or non-stop inflation	Pull the cuff to deflate. Stop using the device and contact us.
	Another	Keep arms, body still, measure again.

No compressive value is displayed or the value does not change or changes erratically when the cuff is inflated	Pull the cuff to deflate. Stop using the device and contact us.
Other phenomena	Turn on the power again and restart the operation. Change the battery. If not, please contact us.

Chapter 17 Keys and Symbols

Symbol	Information
	Manuals/user guides.
SYS	systolic pressure
FOLDER	Average pressure
HE	diastolic pressure
PR	pulse rate (bpm)
ADU	Mature
PED	Child
NEO	Neonates
INFO	Information
	Open prompt voice indication
	Close prompt voice indication
	Low power

	full power
	1. No NIBP data to review 2. No finger inserted into the SpO2 probe (This item is only suitable for EU market) 3. Signal insufficient indicator
	ClassII equipment
	WEEE (2002/96/EC)
	Type BF Applied Part
SN	Serial number
	This item is compliant with Medical Device Directive 93/42/EEC of June 14, 1993, a directive of the European Economic Community.
	European Representative

	USB socket connecting SpO2 probe (This item is only suitable for EU market)
	Interface for connecting the cuff
	Socket for power adapter

Chapter 18 Maintenance, Cleaning and Maintenance

* Please observe the precautions and proper operating methods in this user guide. Otherwise, we will not be responsible for any errors.

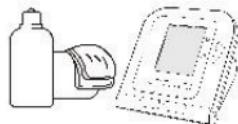
⚠ Warning ⚠

Remove the battery before cleaning. Accessories and main unit must be separated for cleaning.
Maintenance is not allowed while the device is using.

Do not press the rubber tube on the cuff.

⚠ Warning ⚠

- High pressure disinfection of devices and accessories is not permitted.
- Do not allow water or cleaning agents to run into the socket to avoid damaging the device.
- Do not immerse the device and accessories in liquid.
- If damage or deterioration of devices and accessories is found, do not use them.



Maintenance:

- Clean the device and accessories regularly. It is recommended to clean it every month. When the device or accessory gets dirty, use a dry, soft cloth to wipe. If it is very dirty, it is available to dip a soft cloth in water or a mild detergent, and wring it out, then use the cloth to clean.
- The devices should be checked and calibrated periodically (or obey the requirements of the

hospital). It is available for inspection at state designated inspection bodies or by private professionals, or you can contact our company. Long press the "USER" button on the main interface for 5 seconds to enter the calibration interface.

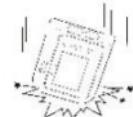
⚠️ Suggestion ⚠️

- Do not use gasoline, essential oils, thinners, etc. to wipe the device.
- Do not clean or wet the cuff.

Storage:

⚠️ Suggestion ⚠️

- Do not expose the device to direct sunlight for a long time, otherwise the screen display may be damaged.
- The basic performance and safety of the device are not affected by dust or cotton in the home environment, and the device should not be placed in high temperature, humidity or dust places.
- Old cufflinks may cause inaccurate measurements, please replace the cuff periodically according to the user manual.
- To avoid damage to the device, keep the device out of reach of children and pets.
- Avoid devices that are close to extreme high temperatures such as fireplaces, otherwise the performance of the device may be affected.
- Do not store the device with chemicals or corrosive gases.
- Do not place the device where there is water.
- Do not place the device where it is subject to tilt, vibration, or impact
- Remove the battery if the device will not be used for three months or more.



Chapter 19 NIBP Specification

Name	Electronic Sphygmomanometer		
Display Mode	2.9" color LCD Display		
Degree of protection against water ingress	IPX0		
NIBP specification			
Measurement Method	Oscillometric method		
working mode	Automatic		
Operation mode	Continuous operation		
Measurement distance	Pressure	adult	0~255 mmHg(0~ 38.6 kPa)
		pediatric	0~200 mmHg(0~ 31.1 kPa)
		neonatal	0~121 mmHg(0~ 18.6 kPa)
	Pulse: 30~250/min		
Over pressure protection	Adult mode	255±5 mmHg (39.33 ± 0.67 kPa)	
	Pediatric fashion	200±5 mmHg (32 ± 0.67 kPa)	
	Neonatal mode	121±5 mmHg (19.33± 0.67 kPa)	
Inflation	Adult	160 ±5 mmHg (21.3 3± 0.67 kPa)	

	Pediatric	$120 \pm 5 \text{ mmHg} (16 \pm 0.67 \text{ kPa})$
	Neonatal	$70 \pm 5 \text{ mmHg} (9.33 \pm 0.67 \text{ kPa})$
Prompt Range	Adult mode	SYS: 40~270 mmHg DIA: 10~215 mmHg
	Pediatric fashion	SYS: 40~200 mmHg DIA: 10~150 mmHg
	Neonatal mode	SYS: 40~135 mmHg DIA: 10~100 mmHg
Resolution	Pressure	1 mmHg (0.133 _ kPa)
Accuracy	Static pressure	$\pm 3 \text{ mmHg} (\pm 0.4 \text{ kPa})$
Error	The BP value of the device is equivalent to the Stethoscope measurement value. Error fulfilling request in ANSI/AAMI SP-10:2002+A1:2003 +A2:2006	
Operating temperature/humidity	+5 °C~40 °C	15 % RH~80 % RH (Non-condensing)
Transport	Transportation by public transportation or according to the contract order, avoid bumping, shaking and splashing by rain and snow in	

	transportation.
Storage	Temperature: -20°C ~ +55°C; Relative humidity: ≤95% ; No corrosive and drafty gases.
Atmospheric pressure	800 hPa ~ 1050 hPa
Power supply	4 x "AA" batteries , AC Adapter (AC, 100 V-240 V, optional)
Rated current	≤600 mA
Battery life	When the temperature is 23°C , the leg circumference is 270 mm, the measured blood pressure is normal, 4 x "AA" batteries can be used about 300 times
Dimension	122 (L) x 110 (W) x 81 (H) mm
Net weight	±328 grams
Safety classification	Class II Equipment (power supplied by power adapter)/Internal powered equipment (power supplied by battery) Type the applied part BF
Service life	The life of the device is five years or 10,000 times the BP measurement.
Production Date	See the label

Accessories

Standard Configuration:
Adult Cuff: 22~32 cm
Pediatric Cuff: 18~26cm
Neonate Cuff: 6~11cm
SpO₂ sensor: Adult, Pediatric, Neonatal; Software CD, User Manual, USB data line, four “AA” batteries
AC Adapter
Input
Voltage: AC100V~240V
Frequency: 50Hz/60Hz
Output
DC5.0V-6.0V 1.0-2.0 A

Chapter 20 SpO₂ Specification

Name	SpO ₂ probe	
Measurement distance	SpO ₂ Measuring Range: 0%~100 %; Pulse Rate Measuring Range: 30 bpm~250 bpm;	
Resolution		
SpO ₂	1 %	
PR	1 bpm	
Measurement Accuracy		
SpO ₂ ,	70 % ~ 100%	± 2 %
	0 %~69 %	undefined
PR	±2 bpm or ±2 % (choose bigger)	
Measurement Performance Under Weak Charging Condition		
pulse charge ratio: 0.4%	SpO ₂ error	±4 % ,
	pulse rate error	± 2 bpm or ±2 % (choose bigger)
Optical Sensor		
Red light	the wavelength is 660 nm , 6.65 mW	
infrared	the wavelength is 880 nm, 6.75 mW	

Attachment

Manufacturer's guidelines and statements – electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Manufacturer's guidelines and statements – electromagnetic emissions		
This device is intended for use in the electromagnetic environment specified below. Device user customers must ensure that the device is used in such an environment.		
Emission test	Obedience	Electromagnetic environment – guide
RF emission CISPR 11	Group 1	The device uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are unlikely to cause interference to nearby electronic equipment.
RF emission CISPR 11	Class B	This device is suitable for use in all enterprises, including domestic enterprises and those connected directly to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC61000-3-2	Class A	
Voltage fluctuation/flicker emission IEC61000-3-3	Fulfill	

Manufacturer's guidelines and statements – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Manufacturer's guidelines and statements – electromagnetic immunity			
This device is intended for use in the electromagnetic environment specified below. The customer or user of the device must ensure that the device is used in such an environment.			
Immunity test	IEC 60601 pengujian test rate	Compliance level	Electromagnetic environment - guide
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	The floor must be wood, concrete or ceramic tile. If the floor is covered with synthetic materials, the relative humidity should be at least 30%.
Electric fast transients/blast s IEC 61000-4-4	±2 kV for power supply line	±2 kV for power supply line	The quality of electrical power should be like that of a typical commercial or hospital environment.
spike IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	The quality of electrical power should be like that of a typical commercial or hospital environment.

<p>Voltage drops, short faults and voltage variations on the power supply input line IEC 61000-4- 11</p>	<p>$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 5 sec</p>	<p>$<5\% U_T$ ($>95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $<5\% U_T$ ($>95\%$ dip in U_T) for 5 sec</p>	<p>The quality of electrical power should be like that of a typical commercial or hospital environment. The device can continue operation during a power failure due to battery usage.</p>
<p>Power frequency (50/60Hz) magnetic field IEC61000-4-8</p>	<p>3A/m</p>	<p>3A/m</p>	<p>The quality of electrical power should be like that of a typical commercial or hospital environment.</p>
<p>NOTE: U_T is the ac mains voltage before the application of the test level.</p>			

Manufacturer's guidelines and statements – electromagnetic immunity – for EQUIPMENT AND SYSTEMS THAT DO NOT SUPPORT LIFE

Manufacturer's guidelines and statements – electromagnetic immunity			
Immunity test	IEC 60601 pengujian test rate	Compliance level	Electromagnetic environment - guide
Conducted RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment shall not be used closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the transmitter frequency. Recommended separation distance $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF	3 V/m	3 V/m	

IEC61000-4-3	80 MHz to 2.5 GHz	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P is the transmitter's maximum output power rating in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>The field strength of a fixed RF transmitter, as determined by an electromagnetic site survey, a must be less than the compliance level in each frequency range.b</p> <p>Interference may occur in the vicinity of equipment marked with the following</p>
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			<p>symbols:</p> 
NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.		
<p>A field strength from fixed transmitters, such as base stations for radio (cellular/wireless) and land mobile radio, amateur radio, AM and FM radio broadcasts and TV broadcasts cannot be predicted with theoretical accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the device is used exceeds the applicable RF compliance level above, the device must be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as device reorientation or relocation.</p> <p>B In the frequency range 150 kHz to 80 MHz, the field strength must be less than 3 V/m.</p>			

Recommended separation distance between portable and mobile RF communication equipment and EQUIPMENT or SYSTEMS – for EQUIPMENT or SYSTEMS NOT SUPPORTING LIFE

The recommended separation distance between portable and mobile RF communication equipment and devices

This device is intended for use in electromagnetic environments where emitted RF interference is controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.

Transmitter's maximum output power rating (P)	Separation distance according to transmitter frequency (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$

0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

For transmitters with maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the transmitter frequency, where P is the transmitter's maximum output power rating in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

⚠ Warning ⚠

- Active medical devices are subject to special EMC precautions and must be installed and used in accordance with these guidelines.
- Electromagnetic fields can affect the performance of the device, so other equipment used in close

proximity to the equipment must meet the appropriate EMC requirements. Cell phones, X-rays, or MRI devices may be sources of interference, as they emit high-intensity electromagnetic radiation.

- Use of ACCESSORIES, transducers and cables other than those specified, with the exception of transducers and cables sold by the device MANUFACTURER as replacement parts for internal components, may result in increased EMISSIONS or a decrease in ME EQUIPMENT or ME SYSTEM IMMUNITY.
- The device must not be used in close proximity to or stacked with other equipment, if necessary, observe and verify that the device can operate normally in the configuration.
- The device or system may still be interfered with by other equipment, even if the other equipment meets the requirements of the relevant national standard.
- This device requires special precautions for electromagnetic compatibility (EMC) and requires qualified personnel to install and use in accordance with the EMC information provided below.
- The device must not touch the connector pins marked with the ESD warning symbol, unless electrostatic discharge precautions are used, the device must not be connected to this connector.
- In order to avoid the accumulation of electrostatic charges, it is recommended to store, maintain and use the equipment at a relative humidity of 30% or more. Floors should be covered with ESD carpet or similar material. In the use of components, non-synthetic clothing should be worn.
To prevent electrostatic discharge to ESD-sensitive parts of the device, personnel should contact the

metal frame of the component or large metal objects near the device. When using the device, especially where it is possible to contact ESD-sensitive parts of the device, the operator should wear a grounded wristband designed for ESD-sensitive devices. For more information on proper use, please refer to the instructions provided with the bracelet.

All potential users are advised to understand the ESD warning symbols and receive training on ESD precautions.

The most basic features of ESD precautionary procedures training should include an introduction to the physics of electrostatic charges, voltage levels in conventional containers, and the breakdown of electronic components when an operator with an electrostatic charge contacts them. In addition, methods to prevent electrostatic build-up, and the means and reasons for the discharge of static electricity from the human body to the ground or equipment frame or the use of wristbands to connect the human body to equipment or the ground before making the connection should be explained.

The following types of cables must be used to ensure that they meet radiation and interference immunity standards:

name a	Length (m)
Power adapter cable	± 1.5
SpO ₂ probe cable	± 1.0

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